(2) Give to the patient a summary in writing of the federal law and regulations.

(b) *Required elements of written summary.* The written summary of the federal law and regulations must include:

(1) A general description of the limited circumstances under which a part 2 program may acknowledge that an individual is present or disclose outside the part 2 program information identifying a patient as having or having had a substance use disorder;

(2) A statement that violation of the federal law and regulations by a part 2 program is a crime and that suspected violations may be reported to appropriate authorities consistent with §2.4, along with contact information;

(3) A statement that information related to a patient's commission of a crime on the premises of the part 2 program or against personnel of the part 2 program is not protected;

(4) A statement that reports of suspected child abuse and neglect made under state law to appropriate state or local authorities are not protected; and

(5) A citation to the federal law and regulations.

(c) *Program options.* The part 2 program must devise a notice to comply with the requirement to provide the patient with a summary in writing of the federal law and regulations. In this written summary, the part 2 program also may include information concerning state law and any of the part 2 program's policies that are not inconsistent with state and federal law on the subject of confidentiality of substance use disorder patient records.

§2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a part 2 program from giving a patient access to their own records, including the opportunity to inspect and copy any records that the part 2 program maintains about the patient. The part 2 program is not required to obtain a patient's written consent or other authorization under the regulations in this part in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of this information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under §2.12(d)(1).

Subpart C—Disclosures With Patient Consent

§2.31 Consent requirements.

(a) *Required elements for written consent.* A written consent to a disclosure under the regulations in this part may be paper or electronic and must include:

(1) The name of the patient.

(2) The specific name(s) or general designation(s) of the part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.

(3) How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed.

(4)(i) *General requirement for designating recipients.* The name(s) of the individual(s) or the name(s) of the entity(-ies) to which a disclosure is to be made.

(ii) *Special instructions for entities that facilitate the exchange of health information and research institutions.* Notwithstanding paragraph (a)(4)(i) of this section, if the recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity(-ies) and

(A) The name(s) of individual or entity participant(s); or

(B) A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed. When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed

pursuant to the general designation (see § 2.13(d)).

(5) The purpose of the disclosure. In accordance with § 2.13(a), the disclosure must be limited to that information which is necessary to carry out the stated purpose.

(6) A statement that the consent is subject to revocation at any time except to the extent that the part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third-party payer

(7) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.

(8) The signature of the patient and, when required for a patient who is a minor, the signature of an individual authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of an individual authorized to sign under § 2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.

(9) The date on which the consent is signed.

(b) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through reasonable diligence could be known, by the individual or entity holding the records to be materially false.

[82 FR 6115, Jan. 18, 2017, as amended at 85 FR 43037, July 15, 2020]

§ 2.32 Prohibition on re-disclosure.

(a) *Notice to accompany disclosure.* Each disclosure made with the patient's written consent must be accompanied by one of the following written statements:

(1) This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65; or

(2) 42 CFR part 2 prohibits unauthorized disclosure of these records.

(b) [Reserved]

[83 FR 251, Jan. 3, 2018, as amended at 85 FR 43037, July 15, 2020]

§ 2.33 Disclosures permitted with written consent.

(a) If a patient consents to a disclosure of their records under § 2.31, a part 2 program may disclose those records in accordance with that consent to any person or category of persons identified or generally designated in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

(b) If a patient consents to a disclosure of their records under § 2.31 for payment or health care operations activities, a lawful holder who receives such records under the terms of the written consent may further disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out payment and/or health care operations on behalf of such lawful holder. In accordance with § 2.13(a), disclosures under this section must be limited to that information which is necessary to carry out the stated purpose of the disclosure. Examples of permissible payment or health care operations activities under this section include:

(1) Billing, claims management, collections activities, obtaining payment under a contract for reinsurance,